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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,395	08/22/2007	Guido Grandi	002441.00212	9708

27476 7590 08/15/2008

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
08/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,395	GRANDI ET AL.	
	Examiner	Art Unit	
	PADMA V. BASKAR	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,11,12,15,18,21,26,28,30 and 31* is/are pending in the application.

4a) Of the above claim(s) *11,12,21, 26,28,30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,15 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/9/07* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/1/06 and 6/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment and response to restriction filed on 6/5/08 is entered.

Election/Restrictions

2. Applicant's election with traverse of Group I, SEQ.ID.NO:55 in the reply filed on 6/5/08 is acknowledged.

The traversal is on the ground(s) that the previously pending claims were subject to restriction that there is no single general inventive concept under PCT Rule 13.1 and Rule 13.2 because WO 02/02606 discloses a polypeptide comprising an amino acid sequence as presented in instant SEQ ID NO:54. However , the claims as amended are drawn to compositions and methods involving a polypeptide as shown in SEQ ID NO:55 or SEQ ID NO:86. These sequences are not present in WO 2002/02606. Thus, unity of invention is present.

This is not found persuasive because Kalman et al (Accession number E7 2033) disclose a polypeptide comprising the (680) amino acid sequence, which is 100% identical to the claimed polypeptide SEQ.ID.NO;55 (please see the sequence alignment in paragraph # 10 below). Therefore, the technical feature of linking groups i.e., method of eliciting an immune response (claims 11, 28, 26 and 30), method of diagnosing an immune response (claims 12, 26 and 31) does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking. Therefore , only claims 1-4, 15, 18, drawn to product with respect to SEQ.ID.NO: 55 will be examined and claims 11-12, 26, 28 and 30-31, drawn to methods are withdrawn as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

3. Claims 1, 11, 15, 26, 28 and 30 have been amended.

Claims 5, 6, 7-10, 13-14, 16, 17, 19, 20, 22 -25, 27 and 29 have been canceled.

Claims 1-4, 11, 12, 15, 18, 21, 26, 28, 30 and 31 are pending.

Claims 11-12, 21, 26, 28 and 30-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/5/08.

Claims 1-4 and 15 and 18 are under examination with respect to SEQ.ID.NO:55.

4. There is no power of attorney present in the application. Applicant is requested to submit the power of attorney.

Specification

5. The Brief Description of the Drawings is objected to because Figures 2A , 2B, 5A and 5B are not described in the Brief description of the Drawings. "For example, if the drawings show Figures 2A and 2B, and the brief description of the drawings refers only to Figure 2, this is an error in the specification which must be corrected, rather than an application filed without all figures of drawings." See MPEP 601.01(g). Appropriate correction is required.

Information Disclosure Statement

6. The Information Disclosure Statements filed on 9/1/06 and 6/16/08 have been reviewed and a signed copy of each is attached to this office action.

Claim Rejections - 35 USC 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

8. Claims 1-4, 15 and 18 are rejected under 36 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As written, do not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

The product " A polypeptide" and "The polypeptide" in claims 1-4 has the same characteristics as that found in nature because *a polypeptide ,* SEQ.ID.NO: 55 is expressed in and can be obtained from *Chlamydia pneumoniae* infected individuals . To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations, which would distinguish the characteristics of applicant's product from the product, as it exists in

nature. It is further suggested that such limitation include the terminology " purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's protein is "free of" relative to the natural source. (see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970). See MPEP 2105.

9. Claims 1-4, 15 and 18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, second paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-4 , 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of “for use as auto transporter antigen" in claim 1 is vague and indefinite as it is not clear what is the use of this polypeptide.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number: E 72033 .

Claims 1-4 are drawn to a polypeptide for use as an auto transporter antigen, the polypeptide comprising the amino acid sequence shown in SEQ ID NO: 55, where use is as an antigen for raising a *Chlamydia pneumoniae* specific immune response, wherein the use is for raising a systemic immune response in an individual infected with Chlamydia pneumoniae, said polypeptide is secreted into the cytoplasm of the host cell through a Type V auto transporter secretion system mechanism.

Accession number: E 72033 as shown below discloses a polypeptide comprising 684 amino acid sequence (from *Chlamydia pneumoniae*. The disclosed polypeptide sequence is 100% identical to the claimed polypeptide sequence (see the sequence alignment). Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Therefore, the disclosed polypeptide that is identical with the claimed polypeptide would be secreted into the cytoplasm of the host cell through a Type V auto transporter secretion system mechanism.

Limitations "use is as an antigen for raising a *Chlamydia pneumoniae* specific immune response", "use is for raising a systemic immune response" are considered as intended use of the polypeptide. Therefore, the prior art polypeptide reads on claims 1-4. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey; 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the prior art anticipated the claimed invention.

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E72033
hypothetical protein - Chlamydophila pneumoniae (strain CWL029)
C;Species: Chlamydophila pneumoniae, Chlamydia pneumoniae
C;Date: 23-Apr-1999 #sequence_revision 23-Apr-1999 #text_change 09-Jul-2004
C;Accession: E72033
R;Kalman, S.; Mitchell, W.; Marathe, R.; Lammel, C.; Fan, J.; Olinger, L.; Grimwood, J.; Davis,
       R.W.; Stephens, R.S.
Nature Genet. 21, 385-389, 1999
```

A;Title: Comparative genomes of Clamydia pneumoniae and C. trachomatis.
A;Reference number: A72000; MUID:99206606; PMID:10192388
A;Accession: E72033
A;Status: preliminary
A;Molecule type: DNA
A;Residues: 1-680 <ARN>
A;Cross-references: UNIPROT:Q9Z7B0; UNIPARC:UPI00000C220D; GB:AE001661; GB:AE001363;
NID:g4377104; PIDN:AAD18934.1; PID:g4377107
A;Experimental source: strain CWL029
C;Genetics:
A;Gene: CPn0796

Query Match 100.0%; Score 3488; DB 2; Length 680;
Best Local Similarity 100.0%; Pred. No. 1.6e-201;
Matches 680; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 MQPCLNMSIVRNSALPLPCLSRSETFKKVRSHMKFMKVLTPWIYRKDLWVTAFLLTAIPG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MQPCLNMSIVRNSALPLPCLSRSETFKKVRSHMKFMKVLTPWIYRKDLWVTAFLLTAIPG 60

Qy         61 SFAHTLVDIAGEPRHAAQATGVSGDGKIVIGMKVPDDPFAITVGFQYIDGHLQPLEAVRP 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 SFAHTLVDIAGEPRHAAQATGVSGDGKIVIGMKVPDDPFAITVGFQYIDGHLQPLEAVRP 120

Qy        121 QCSVYPNGITPDGTVIVGTNYAIGMGSVAVKWVNGKVSELPMLPDTLDSVASAVSADGRV 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 QCSVYPNGITPDGTVIVGTNYAIGMGSVAVKWVNGKVSELPMLPDTLDSVASAVSADGRV 180

Qy        181 IGGNRNINLGASVAVKWEDDVITQLPSLPDAMNACVNGISSDGSIIVGTMVDVSWRNTAV 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 IGGNRNINLGASVAVKWEDDVITQLPSLPDAMNACVNGISSDGSIIVGTMVDVSWRNTAV 240

Qy        241 QWIGDQLSVIGTLGGTTSVASAISTDGTVIVGGSENADSQTHAYAYKNGVMSDIGTLGGF 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 QWIGDQLSVIGTLGGTTSVASAISTDGTVIVGGSENADSQTHAYAYKNGVMSDIGTLGGF 300

Qy        301 YSLAHAVSSDGSVIVGVSTNSEHRYHAFQYADGQMVDLGTLGGPESYAQGVSGDGKVIVG 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 YSLAHAVSSDGSVIVGVSTNSEHRYHAFQYADGQMVDLGTLGGPESYAQGVSGDGKVIVG 360

Qy        361 RAQVPSGDWHAFLCPFQAPSPAPVHGGSTVVTSQNPRGMVDINATYSSLKNSQQQLQRLL 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 RAQVPSGDWHAFLCPFQAPSPAPVHGGSTVVTSQNPRGMVDINATYSSLKNSQQQLQRLL 420

Qy        421 IQHSAKVESVSSGAPSFTSVKGAISKQSPAVQNDVQKGTFLSYRSQVHGNVQNQQLLTGA 480
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                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 IQHSAKVESVSSGAPSFTSVKGAISKQSPAVQNDVQKGTFLSYRSQVHGNVQNQQLLTGA 480

Qy        481 FMDWKLASAPKCGFKVALHYGSQDALVERAALPYTEQGLGSSVLSGFGGQVQGRYDFNLG 540
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 FMDWKLASAPKCGFKVALHYGSQDALVERAALPYTEQGLGSSVLSGFGGQVQGRYDFNLG 540

Qy        541 ETVVLQPFMGIQVLHLSREGYSEKNVRFPVSYDSVAYSAATSFMGAHVFASLSPKMSTAA 600
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 ETVVLQPFMGIQVLHLSREGYSEKNVRFPVSYDSVAYSAATSFMGAHVFASLSPKMSTAA 600

Qy        601 TLGVERDLNSHIDEFKGSVSAMGNFVLENSTVSVLRPFASLAMYYDVRQQQLVTLSVVMN 660
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        601 TLGVERDLNSHIDEFKGSVSAMGNFVLENSTVSVLRPFASLAMYYDVRQQQLVTLSVVMN 660

Qy        661 QQPLTGTLSLVSQSSYNLSF 680
                ||||||||||||||||||||
Db        661 QQPLTGTLSLVSQSSYNLSF 680
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Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-4 , 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession number: E 72033 as applied to claims 1-4 above, and further in view of Probost et al U.S. Patent: 6,432,916 B1.

Claims 15 and 18 are drawn to a composition comprising polypeptide SEQ.ID.NO:55 and one or more stimulants, said composition comprising at least two immunogenic *Chlamydia pneumoniae* auto transporter proteins.

Claims 1-4 are discussed and rejected in Paragraph #10 supra. However, the prior art does not teach composition comprising immunostimulant and two immunogenic *Chlamydia pneumoniae* auto transporter proteins. These deficiencies are made up for in the teachings of Probost et al U.S. Patent No: 6,432,916.

Probost et al teach pharmaceutical composition comprising polypeptides and other Chlamydia antigens, in combination with a physiologically acceptable carrier or immunostimulant(column 2, lines 21-42 , claims 1-6, and para # 47). One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to make composition with at least two immunogenic *Chlamydia pneumoniae* proteins of SEQ.ID.NO:55 and immunostimualnt (ie., adjuvant) because the composition can be used for pharmaceutical or vaccine purposes. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to use at least two immunogenic *Chlamydia pneumoniae* polypeptides as taught by Accession number: Q9Z7B0 in combination with immunostimulant as taught by Probost et al for treating Chlamydia infections.

18. Claims 1-4 , 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession number: Q9Z7B0 as applied to claims 1-4 above, and further in view of Murdin et al WO 002001036457.

Claims 1-4 are discussed and rejected in Paragraph #10 supra. However, the prior art does not teach composition comprising immunostimulant and two immunogenic *Chlamydia*

pneumoniae auto transporter proteins. These deficiencies are made up for in the teachings of Murdin et al WO 002001036457.

Murdin et al teach pharmaceutical composition comprising Chlamydia transporter polypeptides, other Chlamydia antigens that are formulated into or with liposome, ISCOM or adjuvant (ie., immunostimulant) to enhance immune response (Page 42, lines 9-25) for treating and preventing *Chlamydia pneumoniae* (see page 41 , line 5 through page 42). One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to make composition comprising polypeptide, SEQ.ID.NO:55 , immunostimualnt (ie., adjuvant) with at least two immunogenic *Chlamydia pneumoniae* proteins of SEQ.ID.NO:55 because the composition can be used for pharmaceutical or vaccine purposes. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to use polypeptides as taught by Accession number: Q9Z7B0 in combination with immunostimulant and at least two immunogenic *Chlamydia pneumoniae* proteins for preparing a pharmaceutical or vaccine composition for treating Chlamydia infections.

Conclusion

19. No claims are allowed.

20. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A

message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert B. Mondesi on 571272-0956.

Respectfully,

/Padma Baskar/
Examiner 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645